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No. 84-290

In the Supreme Court of the United States

October Term, 1984

ORTHO PHARMACEUTICAL CORPORATION,
Petitioner,

vs.

CAROL LYNN WOODERSON,
Respondent.

BRIEF IN OPPOSITION TO A PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF KANSAS

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QUESTIONS PRESENTED FOR REVIEW

Respondent asserts that a Writ of Certiorari should not be issued. The Kansas Supreme Court entered a judgment in this proceeding which should be recognized by this Court and affirmed. Such recognition will dispose of the following issues:

1. The right of a state court to determine and assess compensatory and punitive damages against a defendant who is regulated by the Federal Government and markets its product in that state.

2. The right of a state court to determine the adequacy of prescription drug warnings given the regulation of said subject matter by the Food and Drug Administration.

3. The right of a state court to rule upon the applicability of its own comparative negligence statutes to a case in controversy and/or the submission of an issue of comparative negligence to a jury.

4. The justiciability of issues that have been rendered moot by a decision of the United States Supreme Court.

TABLE OF CONTENTS

QUESTIONS PRESENTED FOR REVIEW 1
OPINIONS BELOW 1
JURISDICTION 1
STATEMENT OF THE CASE 2
SUMMARY 5
REASONS FOR DENYING PETITION—

I. *Silkwood v. Kerr-McGee Corp.*, ... U.S. ....., 104 S. Ct. 615 (1984) 6
II. Decisional Law Supports the Right of the States to Determine the Adequacy of Prescription Drug Warnings 13
III. The Award of Punitive Damages Is Consistent With the Holding in *Silkwood v. Kerr-McGee Corp.*, and Is Supported by the Evidence 19
IV. Under the Circumstances of the Case at Bar, the Petitioner's Allegations Regarding Comparative Fault Are Unfounded and Without Merit 20
V. Given the Overall Applicability of the Holding in *Silkwood*, the Requisite Case or Controversy Is Non Existent and the Issues Presented Are Therefore Non Justiciable 21

CONCLUSION 22

TABLE OF AUTHORITIES

Cases

Baker v. Carr, 396 U.S. 186, 86 S. Ct. 691, 7 L. Ed.2d 663 (1962) 21

Bristol Myers Co. v. Gonzales, 548 S.W.2d 416 (Tex. App. 1976), *Rev'd on other grounds*, 561 S.W.2d 801 (Tex. 1978) 17-18

Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981) 15

Cosmetic, Toiletry & Fragrance Ass'n, Inc. v. State of Minnesota, 440 F. Supp. 1216 (D. Minn. 1977) 8

Fidelity Federal Savings & Loan Ass'n v. Dela Cuesta, 458 U.S. 141, 153, 102 S. Ct. 3014, 3022, 73 L. Ed.2d 664 (1982) 7

Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-143, 83 S. Ct. 1210, 1217-1218, 10 L. Ed.2d 248 (1963) 7

Hamilton v. Hardy [37 Colo. App. 375, 549 P.2d 1099 (1976)] 15

Hines v. Davidowitz, 312 U.S. 52, 67, 61 S. Ct. 399, 404, 85 L. Ed. 581 (1941) 7

I.B.E.W. v. Foust, 442 U.S. 42, 53, 99 S. Ct. 2121, 2128, 60 L. Ed.2d 698 (1979) 12

Jones v. Hittle Service, Inc., 219 Kan. 627, 549 P.2d 1383 (1976) 18

Lindsey v. Ortho Pharmaceutical Corp., 637 F.2d 87 (2d Cir. 1980) 15

McCue v. Norwich Pharmacal Co., (C.A. 1, 1972) 453 F.2d 1033 15

Mahr v. G. D. Searle & Co. [72 Ill. App.3d 540, 564, 28 Ill. Dec. 624, 390 N.E.2d 1214 (1979)] 15

Northern States Power Co. v. State of Minn., 447 F.2d 1143, 1146-47 (8th Cir. 1971), *Aff'd*, 405 U.S. 1035, 92 S. Ct. 1307, 31 L. Ed.2d 576 (1972) 8, 9

Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541 (Ind. App. 1979) 15, 16, 17

Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n, ... U.S. ....., 103 S. Ct. 1713, 75 L. Ed.2d 752 (1983) 7

Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230, 67 S. Ct. 1146, 1152, 91 L. Ed. 1447 (1947) 7

Schwartz v. Texas, 344 U.S. 199, 202-203, 73 S. Ct. 232, 235, 97 L. Ed. 231 (1952) 8

Seley v. G. D. Searle & Co., 67 Ohio St.2d 192, 423 N.E.2d 831 (1981) 15

Silkwood v. Kerr-McGee, ... U.S. ....., 104 S. Ct. 615 (1984) ..... *passim*

Skill v. Martinez, 91 F.R.D. 498 (D. N.J. 1981), *Aff'd*, 677 F.2d 368 (3d Cir. 1982) 16

United Construction Workers v. Laburnum Corp., 347 U.S. 656, 663-664, 74 S. Ct. 833, 836-838, 98 L. Ed. 1025 (1954) 12

Wooderson v. Ortho Pharmaceutical Corp., 235 Kan. 387, 681 P.2d 1038 (1984) 3, 5, 10, 21

Statutes and Regulations

U.S.C.A. Const., Art. 6, Cl. 2 8

21 C.F.R. 1.21(c)(1) 10

21 C.F.R. 201.200 10

21 C.F.R. 201.57 ..... 10, 11

Other Authorities

Restatement (Second) of Torts § 402A, comments j and k 14

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OPINIONS BELOW

The opinion of the Supreme Court of Kansas dated April 27, 1984, reported at 235 Kan. 387, 681 P.2d 1038, are reproduced in Appendix A of petitioner. This was a direct appeal from the judgment entered by the trial court on a verdict returned in February, 1983. On March 18, 1983, the trial court orally denied Ortho Pharmaceutical Corporation's Motions for a Directed Verdict or in the Alternative for a New Trial (R. XL).[1]

JURISDICTION

The Court's decision in *Silkwood v. Kerr-McGee*, ... U.S. ....., 104 S. Ct. 615 (1984), renders moot the issues raised by petitioner and absent the requisite justiciability, this Court is without subject matter jurisdiction to hear the same.

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1. Citations to "R. ....." are to the trial record; "pp. ....." refers to the trial transcript.

STATEMENT OF THE CASE

This is the case of a statistic which has been described as unconvincing and uncorroborated.

Carol Lynn Wooderson brought her action in the District Court of Sedgwick County, Kansas, for damages for personal injuries which she claims resulted from her ingestion, over a period of years, of the oral contraceptive Ortho-Novum 1/80, manufactured by the petitioner, Ortho Pharmaceutical Corporation (Ortho). Mrs. Wooderson alleged that Ortho knew, or should have known, of the dangerous side effects of its products based upon its position as an expert in the field, upon its research, upon cases reported to it, and upon scientific development, research, and publications in the field.

Ortho alleged that scientific studies of its drugs by disinterested research groups had not proven an association between the use of Ortho-Novum 1/80 and Hemolytic Uremic Syndrome (HUS), malignant hypertension, and acute renal failure, and that it therefore, had no duty to warn of the same. Ortho also claimed that, assuming arguendo that they did have knowledge of said side effects, the Food and Drug Administration (FDA) had rejected a proposal from the G. D. Searle & Co. pertaining to the inclusion of HUS as an adverse reaction associated with the use of Ortho-Novum 1/80 because the reports of HUS were anecdotal, and not based on well controlled scientific studies (none of which were conducted by Ortho) in accordance with the statute and regulations.

The Kansas Supreme Court found:

> The expert testimony and the exhibits in this case disclose that there was an abundance of published information in the medical journals, prior to and

during the years when plaintiff was taking Ortho-Novum 1/80, which linked the use of oral contraceptives with HUS, malignant hypertension, and acute renal failure. . . . The available scientific literature clearly tended to show that there was a danger of HUS, malignant hypertension and acute kidney failure attendant to the use of the drug.

Wooderson v. Ortho Pharmaceutical Corp., 235 Kan. 387 at 408-409, 681 P.2d 1038 at 1056-1057 (1984).

The Kansas Supreme Court also found:

On April 10, 1970, Ortho sent a Sales Bulletin on the subject of Ortho-Novum labeling changes to its "detail men," sales representatives of the manufacturer who call directly upon the physicians. That bulletin quoted extensively from the first paragraph of the acting commissioner's (FDA) letter, but made no mention of the third paragraph concerning the British Committee's advice to physicians in England. On May 15, 1970, Ortho sent out another Sales Bulletin, this one on the subject of *The Report of the British Committee on the Safety of Drugs*. This bulletin did not quote the third paragraph of the acting commissioner's letter, but was obviously written in response thereto. It indicated that Ortho's own analysis of the British data indicates that there is no statistically significant difference between 50, 75/80 and 100 micrograms of mestranol. It stated that products containing 75/80 gammas of mestranol show a risk as low if not lower than 50 gamma products. It urged the continued sale of its 80 gamma product, and cautioned its sales people not to be "stampeded" with the number 50. A July 6, 1970, Sales Bulletin continued to urge sale of Ortho-Novum 1/80, and

urged concentration on Ortho-Novum 1/50 only if the physician "is very concerned with using lowest estrogen activity." For physicians who asked about switching patients to lower estrogen level products, the bulletin suggested that detail men respond:

"Doctor, nothing in this British data offers enough sound evidence to cause you to switch patients who are on 100 gamma of mestranol. We have been saying for years and continue to say that it makes sense to use the least activity of any drug that will effectively accomplish its purpose; therefore, you may wish to move patients to low activity products such as ORTHO-NOVUM 1/80 or ORTHO-NOVUM 1/50."

In short, this evidence indicated that Ortho played down the British report and continued to urge sale of its higher estrogen product until Ortho itself could be entirely satisfied that the product was causing damage. Apparently its competitive posture in the market was better served by continuing the manufacture and sale of its 1/80 product, since other manufacturers were also producing the 1/50 dosage.

Another area which plaintiff emphasizes is that of the "Irey-type" lesions. Dr. Nelson S. Irey, of the Armed Forces Institute of Pathology, issued a report in 1969, and published it in a pathology journal in 1970. The blood vessels of some forty women had been examined posthumously. Lesions were found in the inner wall or intima of the blood vessels of every one of the bodies of those women who were known to have been taking oral contraceptives; no such changes were found in the bodies of those who had *not* been taking oral contraceptives. In spite of this report linking oral contraceptives to vessel wall

> damage, Ortho did no further animal research to prove or disprove the proposition put forth by Irey: that oral contraceptives cause vessel wall damage.

Wooderson, supra, at 419.

At the conclusion of a six-week trial, the jury returned a verdict and the Court entered judgment for respondent and against Ortho for actual damages of $2,000,000 and punitive damages of $2,750,000. The Supreme Court of Kansas affirmed the verdict on appeal.

SUMMARY

The respondent submits that once a drug manufacturer has performed a sufficient amount of testing to acquire approval from the Food and Drug Administration, it is duty bound to continue testing and evaluating its products. The manufacturer cannot wait until there is absolute statistical proof to support the need for additional testing and/or the promulgation of warnings necessary to apprise the prescribing physician of the risks associated with the ingestion of their product.

The Kansas Supreme Court's ruling in *Wooderson v. Ortho Pharmaceutical Corp.,* 235 Kan. 387, 681 P.2d 1038 (1984), encourages manufacturers of prescription drugs to adequately test their products so that they will be able to warn of risks attendant with consumption of their product. The petitioner cannot deny that statistically proven results regarding known hazards will be approved by the FDA for labeling, even at the expense of adding "clutter" to an extended list of warnings that must accompany the distribution of prescription drugs within a given state.

Respondent further submits that the goals of the Food and Drug Administration are to regulate the manufacture and marketing of prescription drugs. By its decision, the Kansas Supreme Court is not attempting to promulgate laws governing the manufacture or marketing of prescription drugs. They are not impinging upon the bailiwick of the Food and Drug Administration in any way. This is a civil action in which the Kansas Courts, through the application of common law principles of negligence and strict liability in tort, are protecting the rights of its citizens.

REASONS FOR DENYING PETITION

I. Silkwood v. Kerr-McGee Corp., ... U.S. ....., 104 S. Ct. 615 (1984).

The State's traditional authority to provide tort remedies to its citizens and the Federal Government's regulatory authority in certain spheres of interest are to be considered in the case at bar.

Amicus would characterize this Court's holding in *Silkwood*, as an expression of the proposition that State tort remedies enjoy no special immunity from Federal preemption.

The petitioners tell us that the State's ability to grant an award of punitive damages, in an industry that is regulated by the Federal Government, was left open by this Court's decision in *Silkwood*.

Respondent respectfully submits that the foregoing arguments of counsel constitute a "mislabeling" of this Court's holding in *Silkwood* and the rationale therefor.

In *Silkwood*, this Court held that:

> Insofar as damages for radiation injuries are concerned, preemption should not be judged on the basis that the federal government has so completely occupied the field of safety that state remedies are foreclosed but on whether there is an irreconcilable conflict between the federal and state standards or whether the imposition of a state standard in a damages action would frustrate the objectives of the federal law.

....., 104 S. Ct. at 622, 626.

As this Court recently observed in *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, ... U.S. ....., 103 S. Ct. 1713, 75 L. Ed.2d 752 (1983), State law can be preempted in either of two general ways. If Congress evidences an intent to occupy a given field, any State law falling within that field is preempted. *Id.* at ....., 103 S. Ct. 1722; *Fidelity Federal Savings & Loan Ass'n v. Dela Cuesta*, 458 U.S. 141, 153, 102 S. Ct. 3014, 3022, 73 L. Ed.2d 664 (1982); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S. Ct. 1146, 1152, 91 L. Ed. 1447 (1947). If Congress has not entirely displaced State regulation over the matter in question, state law is still preempted to the extent it actually conflicts with Federal law, that is, when it is impossible to comply with both State and Federal law, *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143, 83 S. Ct. 1210, 1217-1218, 10 L. Ed.2d 248 (1963), or where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress, *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S. Ct. 399, 404, 85 L. Ed. 581 (1941). *Pacific Gas & Electric Co., supra*, at ....., 103 S. Ct. at 1722.

The Court initially must approach the question of Federal preemption from the viewpoint that a finding of preemption is the exception rather than the rule. *Cosmetic, Toiletry & Fragrance Ass'n, Inc. v. State of Minnesota,* 440 F. Supp. 1216 (D. Minn. 1977), U.S.C.A. Const., Art. 6, Cl. 2.

If Congress is authorized to act in a field, it should manifest its intention clearly It will not be presumed that a Federal statute was intended to supersede the exercise of the power of the State unless there is a clear manifestation of intention to do so. The exercise of Federal supremacy is not lightly to be presumed. *Schwartz v. Texas,* 344 U.S. 199, 202-203, 73 S. Ct. 232, 235, 97 L. Ed. 231 (1952).

Given this point of departure, the Court must examine the language and purpose of the Federal statute, its legislative history, its field of operation, and points of literal and practical conflict between the Federal and State enactments to determine whether the heavy burden of demonstrating preemption has been met.

A comprehensive opinion dealing with the format for judicial analysis when a preemption issue is raised is that of former Chief Judge Matthes in *Northern States Power Co. v. State of Minn.,* 447 F.2d 1143, 1146-47 (8th Cir. 1971), *Aff'd,* 405 U.S. 1035, 92 S. Ct. 1307, 31 L. Ed.2d 576 (1972). The prescribed analysis is basically four tiered. In this case, the second and fourth steps are disputed. That is, with regard to steps one and three, no one contends that the FDA exceeded its statutory authority in promulgating the Federal rules in question, that Congress acted unconstitutionally in permitting this type of regulation under the Food, Drug and Cosmetic Act, or of critical importance herein, that the Food, Drug

and Cosmetic Act contains express preemption provisions. Of issue herein is the doctrine of implied preemption and, as alleged by the petitioner and Amicus, the physical impossibility of compliance with the Federal regulations and tort law concepts respecting the same.

In regard to the issue of implied preemption, Judge Matthes, in *Northern States Power Co.*, articulated four key factors in determining whether preemption of a particular area of regulation has occurred. These factors, distilled from the many cases which have considered preemption questions, are:

> (1) The aim and intent of Congress as revealed by the statute itself and its legislative history . . .; (2) The pervasiveness of the federal regulatory scheme as authorized and directed by the legislation and as carried into effect by the federal administrative agency . . .; (3) The nature of the subject matter regulated and whether it is one which demands "exclusive federal regulation in order to achieve uniformity vital to national interests." . . .; and (4) "Whether under the circumstances of [A] particular case [state] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Northern States Power Co., supra,* at 1146-47).

Turning to the first of these four factors, the petitioner and Amicus have cited numerous regulations, abstract portions of legislative history, and have tacked the same together to resemble an argument.

The petitioner would have this Court believe that not only does the FDA proscribe minimum requirements for labeling purposes, but that they proscribe "optimal" requirements. In support of this proposition, the peti-

tioner argues that the FDA's rejection of some 15 proposed labeling changes, including "some" language pertaining to Hemolytic Uremic Syndrome (the record is devoid of any evidence respecting the actual language employed), when read together with 21 C.F.R. 1.21(c)(1), is clearly indicative of the FDA's position with respect to the non-inclusion of HUS as a possible side effect or adverse effect of that drug which is the subject matter of the case at bar.

The Kansas Supreme Court addressed this proposition and rejected the same noting:

> The letter cannot be construed as a clear determination by the FDA that contraceptive induced HUS does not merit warnings and thus this argument has no merit.

Wooderson v. Ortho Pharmaceutical Corp., supra, at 409.

The Amicus have also abstracted selected portions of legislative history dealing with the definitional sections of 21 C.F.R. 201.57 and have read the same together with 21 C.F.R. 201.200 dealing with the efficacy claims of drug manufacturers. The Amicus would then submit to this Court that the limiting language of the efficacy section and the corresponding proof required under 21 C.F.R. 201.200 to obtain an "effective" classification from the National Academy of Sciences-National Research Council-Drug Efficacy Study Group, somehow supports the proposition that warnings without absolute documentation or representative studies respecting the same will be prohibited by the FDA. The pathetic conclusion of such a proposition is inescapable, i.e., until the control group (the consumer) has a representative number of casualties, and a disinterested research foundation, such as the British Committee on Safety of Drugs, initiates an

investigation pertaining to the incidence of injury and subsequently develops proof pertaining to the same, that the manufacturer is in the meantime "prohibited" from warning the consumer of "undocumented" suspected adverse reactions for which "an association has neither been confirmed nor refuted" and is thereby isolated from liability respecting the same.

Fortunately, for the sake of the consumer, this Court, by virtue of its decision in *Silkwood,* still permits the states and a jury of one's peers, to decide each case upon the evidence submitted in order to determine whether or not the manufacturer in question is responsible for its failure to test and warn individuals, such as the plaintiff herein, who has become an unconvincing and uncorroborated statistic.

In regard to the second factor of the preemption considerations, this respondent readily concedes that Congress, through the Food and Drug Administration, has expressed an intent to occupy the field in terms of the manufacture and distribution of prescription drugs. Congress has, through the FDA, gone one step further in terms of labeling requirements and admonitions pertaining to efficacy claims of the manufacturer. 21 C.F.R. § 201.57, et seq.

As was true in *Silkwood,* any evidence of the intent of Congress to preclude the States from providing traditional State law remedies for its citizens, is conspicuously absent from the Briefs of the petitioner and Amicus and more importantly, from the dispositive regulations concerned. As this Court noted in *Silkwood*:

> This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, re-

move all means of judicial recourse for those injured by illegal conduct. *United Construction Workers v. Laburnum Corp.*, 347 U.S. 656, 663-664, 74 S. Ct. 833, 836-838, 98 L. Ed. 1025 (1954).

Unlike *Silkwood*, and in support of the respondent's position, there is no legislation akin to that of the Price-Anderson Act which evidenced an intent by Congress to make compensation available to victims of a nuclear accident.

In regard to the third and fourth factors in preemption questions, this Court must decide whether or not the subject matter regulated is one which demands "exclusive federal regulation in order to achieve uniformity vital to national interests" and whether or not, under the circumstances of a particular case [State] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. At the risk of belaboring this point, the respondent would concur with this Court's conclusion in *Silkwood*, which is applicable herein, wherein it was noted that by not providing for the same (damages) Congress assumed that traditional principles of State Court law would apply with full force unless they were expressly supplanted. Thus, it is Ortho's burden to show that Congress intended to preclude such awards. *I.B.E.W. v. Foust*, 442 U.S. 42, 53, 99 S. Ct. 2121, 2128, 60 L. Ed.2d 698 (1979) (Blackmun, J., concurring).

By failing to address the issue of remedies, Congress had to assume that State law remedies, in whatever form they might take, were available to injured claimants. This was so, even though Congress was well aware of the FDA's exclusive authority to regulate the manufacture and marketing of prescription drugs.

As this Court notes, in both its majority and dissenting opinions, there will no doubt be tension between the conclusion that safety regulation, and in this case manufacture and marketing regulation, is the exclusive concern of the Federal law and the conclusion that a State may nevertheless award damages based on its own law of liability.

It may be that the award of damages based upon a State's law of negligence or strict liability is regulatory in the sense that, in this case a pharmaceutical manufacturer, will be threatened with damages liability if it does not conform with State standards, but that regulatory consequence was something that Congress was quite willing to accept.

As far as damages caused by pharmaceuticals are concerned, the test should be a reflection of this Court's holding in *Silkwood,* i.e.:

> The preemption should not be judged on the basis that the federal government has so completely occupied the field of safety that state remedies are foreclosed but on whether there is a irreconcilable conflict between the federal and state standards or whether the imposition of a state standard in a damages action would frustrate the objectives of the federal law.

The facts in the case at bar, perhaps even more so than the facts in *Silkwood,* militate in favor of finding no such conflict or frustration.

II. Decisional Law Supports the Right of the States to Determine the Adequacy of Prescription Drug Warnings.

Carol Wooderson produced evidence sufficient for the jury to conclude there is an association between the use of oral contraceptives and Hemolytic Uremic Syndrome,

malignant hypertension and acute kidney failure. Given this association, Ortho was obliged to include warnings of that association. Since there is evidence to support the jury's conclusion that an association exists, Ortho is not entitled to now remarshal those facts favorable to its argument in hopes that this Court will sit as a second trier of facts.

Defendant, according to its argument in the lower Courts, would have the Court believe Comments j and k of Section 402A, Restatement (Second) of Torts, somehow provide them with a blank check to market dangerous drugs however they see fit, yet never have to pay the piper. According to the defendant, Comment j requires "proof the drug maker has knowledge or by application of reasonably developed human skill and foresight should have knowledge of the presence of an increased risk." (Appellant's Brief at 11). In fact, Comment j speaks of "knowledge of the presence of *the ingredient* and the danger. Likewise, in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required." This case is about an unduly dangerous drug, not about eggs or strawberries, nor about alcoholic beverages or saturated fats.

According to the petitioner and Amicus, the seller is not responsible "unless he fails to give proper warning of the risks" which responsibility is held in check by the regulatory scheme of the Food and Drug Administration. In the lower Courts, the petitioner's assertion was capsulized in the defendant's Proposed Instruction No. 16 which, as indicated above, states that the seller is not responsible "unless he fails to give proper warning of the risks." This, however, was the substance of the instructions given.

The manufacturer of a dangerous drug is duty bound to provide an adequate warning. *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541 (Ind. App. 1979). Unless the FDA requires otherwise, as it does with oral contraceptives (R. LXXV, pp. 38-39), the warnings need only be made to the doctor. *Lindsey v. Ortho Pharmaceutical Corp.*, 637 F.2d 87 (2d Cir. 1980). Still when information is provided by the manufacturer, it must not mislead and misinform the recipient. *Seley v. G. D. Searle & Co.*, 67 Ohio St.2d 192, 423 N.E.2d 831 (1981). Carol Wooderson testified she was misled by Ortho's patient information booklet. (Exhibit 6, R. XXXXVI, p. 8; R. VI, pp. 114, 120-124, 137-144). Ortho's effort to duck its responsibility to warn of the risk of Hemolytic Uremic Syndrome, malignant hypertension and kidney failure is based upon the theory that if one does not know to a scientific certainty, one need not do anything. This is not the law.

> A jury may find that a warning is inadequate and unreasonable even where the existence of a "risk," i.e., a causal relationship between the use of the product and resulting injury, has not been definitely established. *McCue v. Norwich Pharmacal Co.*, (C.A. 1, 1972) 453 F.2d 1033; *Hamilton v. Hardy* [37 Colo. App. 375, 549 P.2d 1099 (1976)]. Thus, where scientific or medical evidence exists tending to show that a certain danger is associated with use of the drug, the manufacturer may not ignore or discount that information in drafting its warnings solely because it finds it to be unconvincing. *Mahr v. G. D. Searle & Co.* [72 Ill. App.3d 540, 564, 28 Ill. Dec. 624, 390 N.E.2d 1214 (1979)].

Seley v. G. D. Searle & Co., 423 N.E.2d at 837.

In *Skill v. Martinez,* 91 F.R.D. 498 (D. N.J. 1981), *Aff'd,* 677 F.2d 368 (3d Cir. 1982), Ortho is singing another verse of the same tune. Plaintiff suffered a cerebral vascular accident, or a stroke, resulting from her ingestion of an unspecified dosage of Ortho Novum in conjunction with smoking. When Ortho's argument that Mrs. Skill had to prove the cause of her stroke to an absolute certainty was rejected, there was still Ortho's first fall back position. There was, Ortho insisted, no duty to warn. Ortho argued the warnings about the risks of stroke were admittedly adequate, and these warnings should be enough. There was, however, no warning about smoking while on the pill.

> Ortho argues that the medical literature did not support the jury's finding that the drug company should have warned of this risk. It opines that it is not sufficient for respected scientists to indicate that the risk of stroke was greater when pills are taken combined with smoking, because those scientists also say they would like larger samples. The basic question the jury had to answer boiled down to this: Was there sufficient knowledge, at the relevant time, of danger inherent in taking the pill while smoking to compel Ortho's giving of proper warnings in this regard? The jury answered "Yes" and the Court cannot quarrel with that answer.

91 F.R.D. at 514.

In *Ortho Pharmaceutical Corp. v. Chapman,* 388 N.E. 2d 541 (Ind. App. 1979), Ortho offered expert opinion that the causal relationship between oral contraceptives and thrombophlebitis had not been established. It argued "There should be no liability for the failure to state what is not proved true." 388 N.E.2d at 544. The Court held

that the question of the relationship was one for the jury. "Clearly we cannot find as a matter of law that the warnings were adequate." *Id.*

Dr. Pasquale, Ortho's clinical director, testified "If those case reports are reasonable evidence of an association, *we should have changed the package insert, yes*" (R. XXXII, p. 2377). How many pages there are in some medical texts (Appellant's Brief at 15, n. 17), cannot change the content nor the import of the testimony of the clinical director of Ortho Pharmaceutical that if a jury finds it more likely than not that the case reports established "reasonable evidence of an association" then Ortho should have changed the package insert.

Defendant contends that compliance with the Food and Drug Administration requirements somehow lets Ortho off the hook. The jury was properly instructed on this issue in Instruction No. 9:

> Evidence that a manufacturer has complied with applicable regulations or industry standards in the labeling of its product constitutes evidence of due care on the part of the manufacturer but it is not conclusive. Such evidence may be considered by you in determining whether or not the warnings given were adequate. Such a compliance does not relieve a manufacturer of the duties set forth in these instructions.

(R. II, p. 304).

In *Ortho v. Chapman, supra,* the Court noted it could not find the warnings adequate as a matter of law, "nor does Ortho's compliance with federal law require a different result." 388 N.E.2d at 554.

In *Bristol Myers Co. v. Gonzales,* 548 S.W.2d 416 (Tex. App. 1976), *Rev'd on other grounds,* 561 S.W.2d

801 (Tex. 1978), the Court rejected the argument that compliance with FDA requirements makes a warning adequate as a matter of law. On review, this holding was specifically endorsed by the Supreme Court of Texas. 561 S.W.2d at 804.

In *Jones v. Hittle Service, Inc.*, 219 Kan. 627, 549 P.2d 1383 (1976), the Court held compliance with administrative standards was evidence of due care, but that such compliance does not preclude a finding of negligence or a product defect if a reasonable person would do more.

In summarizing Ortho's argument it had no duty to warn, they purport to make four points. Respondent has never demanded "prolix compendium" of anything. Carol Wooderson has simply proved there should have been a warning about Hemolytic Uremic Syndrome, malignant hypertension and acute kidney failure. She has also proved Ortho failed to apprise doctors of the relative risks of various dosages of synthetic estrogen in Ortho-Novum products. She has proved that the risk was real, although Ortho apparently likes to think the loss of both kidneys is minor. There is nothing in the record about what doctors read and what they ignore, and Ortho certainly has not proved that doctors are provided with adequate warnings, they cannot understand or do not believe.

Respondent has proved to the jury's satisfaction that there was substantial evidence of the association between oral contraceptives and Hemolytic Uremic Syndrome, malignant hypertension and acute kidney failure. Even Ortho's clinical director agreed that, on that assumption, "we should have changed the package insert," and that "[w]e would be misbranding" (R. XXXII, p. 2377). Ortho did have a duty to warn, and the jury's finding should

not be disturbed. To ask this Court to review the prior trial and the Kansas Supreme Court's decision is preposterous. This would indeed be a busy Court if it had to review all such State Court decisions.

III. The Award of Punitive Damages Is Consistent With the Holding in Silkwood v. Kerr-McGee Corp. and Is Supported by the Evidence.

Once again, the respondent submits that this Court's holding in *Silkwood* is applicable and dispositive of the Kansas Court's ability to assess punitive damages against a defendant under the circumstances of the case at bar.

As was true in *Silkwood,* the award of punitive damages in this case does not conflict with the Federal remedial scheme under which the FDA is authorized to impose civil penalties on drug manufacturers for violation of Federal standards. Paying both Federal fines and State imposed punitive damages for the same incident is not physically impossible, nor does exposure to punitive damages frustrate any purpose of the Federal remedial scheme. By failing to provide an adequate remedy for those who are injured by prescription drugs, Congress in effect has said that it is not inconsistent to vest the FDA with regulatory authority over the manufacture and marketing of prescription drugs while at the same time allowing plaintiffs like Wooderson to recover for injuries caused by said drugs.

The respondent further submits that this Court need not reach the basis for the jury's award of punitive damages given the applicability of *Silkwood* as aforesaid. In deference to Carol Lynn Wooderson, the respondent does add that the record below is replete with proof respecting the actionable conduct of the petitioner including, but not

limited to, failing to warn of and test for Irey-type lesions after having obtained causational knowledge respecting the same and instructing its salesman to negate the FDA's Dear Doctor letters. Enough said.

IV. Under the Circumstances of the Case at Bar, the Petitioner's Allegations Regarding Comparative Fault Are Unfounded and Without Merit.

Throughout the course of the petitioner's appeals, they have tried repeatedly to remedy their trial strategy in regard to the issue of comparative fault. The Kansas Supreme Court dealt with this particular allegation and disposed of the same by finding that:

> Ortho's position was clearly stated: *It made no claim that the physicians departed from approved medical practice,* and it intended to offer no evidence that the physicians did anything wrong. If the plaintiff's evidence were to disclose fault on the part of the physicians, Ortho reserved the right to argue that. When the matter went to trial, plaintiff offered no evidence of causal negligence on the part of the physicians, and thus it was not necessary for the trial court to submit that issue to the jury. There was no evidence, expert or otherwise, of actionable, causal negligence on the part of Drs. Hermes and Wilcox. Under the circumstances disclosed by the record and the evidence in this case, we conclude that the trial court did not err in refusing to submit the issue of the comparative negligence of the physicians to the jury.
>
> As to the claimed negligence on the part of plaintiff, Ortho points only to the evidence that plaintiff did not go to the hospital emergency room on June 25

after she was told by her physician to do so if she did not get better by 6:00 o'clock that evening. Whether she felt better by evening, we do not know. There is no testimony, medical or otherwise, which suggests that this failure to go to the hospital on June 25, caused or contributed to her injuries or that her condition was reversible on June 25. She saw Dr. Wilcox on June 28, and he did not send her to the hospital at that time. There is, however, testimony that diagnosis and treatment several months earlier might have averted the disaster. We find no evidence to support the submission of Mrs. Wooderson's causal negligence to the jury. (Emphasis supplied by the Kansas Supreme Court) *Wooderson, supra,* at 414.

V. Given the Overall Applicability of the Holding in Silkwood, the Requisite Case or Controvery Is Non Existent and the Issues Presented Are Therefore Non Justiciable.

Baker v. Carr, 396 U.S. 186, 86 S. Ct. 691, 7 L. Ed.2d 663 (1962), and its progeny have established a long line of precedent which has been repeatedly recognized by this Court in a plethora of decisional law. The respondent submits that the facts in the case at bar are perhaps a better example of the fact situation in *Silkwood* for the applicability of holdings therein to the proposition submitted by the respondent.

The respondent respectfully submits that this Court should recognize its holdings in *Silkwood* and the applicability thereof to the case at bar and find therefore that the issues presented are non justiciable.

CONCLUSION

Nine Justices of the Supreme Court act in concert with one another to determine the course of decisional law and in a practical sense, the history of the United States of America. By its holding in *Silkwood*, this Court permits the States to protect their citizens and compensate them when they have been wronged by another.

The petitioner and Amicus repeatedly entreat this Court to undermine the jury's verdict and decide the case the way they argued the facts. They ask the Court to reverse this verdict because, to Ortho, it seems "irrational and unsound."

Many are the cases in which one side or the other feels that the result is irrational and unsound. If this were the test of a verdict, finality would be rare indeed. Carol Wooderson has gotten a verdict to which the evidence shows she is entitled. It should be affirmed. This Court has not and should not establish a policy of reviewing State Court trials and decisions such as this one. The Petition should be denied.

Respectfully submitted,

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